

REMARKSI. Status of the Claims

Claims 5, 6 and 9-16 are pending this the application.

Claims 5, 6, 9-12 and 14-16 were withdrawn by the Patent Office as being drawn to a nonelected invention. Applicants will cancel these claims when the subject application is in condition for allowance.

Claim 13 is pending and stands rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13 also stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Finally, claim 13 was objected to as depending from a non-elected claim.

Claim 13 has been amended in the instant Response. Support for the amendments to claim 13 is found throughout the specification as filed, for example in Figure 3 and the associated Brief Description of Figure 3, on page 45, lines 21-22, and on page 44, line 20 through page 45, line 7.

II. Response to the Patent Office's Contention That the Application
Does Not Comply With the Requirements of 37 C.F.R. §1.821-1.825

The Patent Office states the subject application does not comply with the requirements of 37 C.F.R. §1.821-1.825. Specifically, the Patent Office states "no sequence identification has been provided for the amino acid sequences presented in Figure 3A-3F of the instant specification." *Office Action*, page 2.

The specification has been amended in the description of Figure 3 in the Brief Description of the Figures. Sequence identifiers have been added, along with the names of some of the proteins associated with the sequence identifiers. As the names of the proteins are in Figure 3, no new matter is added.

Applicants enclose a computer readable copy and a paper copy of the substitute sequence listing, as well as a statement of verification. The corrected copies include all the sequences in Figure 3A-3F. Applicants submit that all sequences present in the application now appear in the amended Sequence Listing.

Applicants respectfully request that the substitute sequence listing submitted herewith be entered into the specification.

Applicants submit that the above amendments and remarks overcome the Patent Office's objection and that the Sequence Listing is in compliance with the requirements of 37 C.F.R. §1.821-1.825.

III. Response to the Patent Office's Position Regarding the Information Disclosure Statement

Filed June 23, 2004

The Patent Office states that the Information Disclosure Statement filed on June 23, 2004 does not comply with 37 C.F.R. §1.98(b)(5). The Patent Office further states that documents 2AR and 2AS have not been considered.

Applicants submit herewith under separate cover a supplemental IDS citing documents 2AR and 2AS of the June 23, 2004 IDS that is compliant with 37 C.F.R. §1.98(b)(5).

IV. Response to the Objection to Claim 13

The Patent Office objected to claim 13 as being dependent from a non-elected claim.

Applicants submit that the amendments to claim 13 overcome the Patent Office's objection.

V. Response to the Rejection of Claim 13 Under

35 U.S.C. §112, First Paragraph, Written Description

The Patent Office rejected claim 13 under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) , at the time the application was filed, had possession of the claimed invention." *Office Action*, page 4. The Patent Office states "claim 13 is directed to a method for identification of a substrate for a part of OATP protein. The claim does not require that the part of OATP possesses any particular conserved structure or other disclosed distinguishing feature." *Office Action*, page 4. The Patent office concludes "the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims." *Office Action*, page 4. Applicants traverse the rejection and submit the following comments.

Applicants have amended claim 13 to remove reference to “a part of OATP.” Applicants submit that this amendment to claim 13 overcomes the Patent Office’s rejection and respectfully request that this rejection be reconsidered and withdrawn.

VI. Response to the Rejections of Claim 13 Under
35 U.S.C. §112, Second Paragraph

The Patent Office rejected claim 13 under 35 U.S.C. §112, second paragraph, for several reasons. Applicants address each of these rejections in turn in the following paragraphs.

A. Response to the Rejection Presented in Paragraph 9 of the Office Action

The Patent Office rejected claim 13 under 35 U.S.C. §112, second paragraph as indefinite. More particularly, the Patent Office states “Claim 13 is vague and indefinite in so far as it employs the term ‘OATP’ as a limitation. This term is appears to be novel, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of ‘OATP’.” *Office Action*, page 6. Applicants traverse the rejection and submit the following comments.

Without addressing the merit of the Patent Office’s rejection, applicants have amended claim 13 to recite the element that the OATP is OATP2 and comprises the amino acid sequence of SEQ ID NO:2. Applicants submit that this amendment to claim 13 overcomes the Patent Office’s rejection and respectfully request that this rejection be reconsidered and withdrawn.

B. Response to the Rejection Presented in Paragraph 10 of the Office Action

The Patent Office continues, “Claim 13 is vague and indefinite for recitation ‘capable of being transported’ and ‘potentially capable of being transported’.” *Office Action*, page 7. The Patent Office suggests that the “recitation ‘identifying a compound that is transported by OATP’ would better reflect the inventive concept of the claimed method.” *Office Action*, page 6. Applicants traverse the rejection and submit the following comments.

Without addressing the merit of the Patent Office’s rejection, applicants have adopted the Patent Office’s suggestion and have amended claim 13 to include the recitation “identifying a compound that is transported by OATP.” Applicants submit that this amendment to claim 13

overcomes the Patent Office's rejection and respectfully request that this rejection be reconsidered and withdrawn.

C. Response to the Rejection Presented in Paragraph 11 of the Office Action

Finally, the Patent Office states claim 13 is indefinite "as being incomplete for omitting essential steps, such omission amounting to a gap between the steps." *Office Action*, page 7. The Patent Office states, "The omitted steps are: the step that identifies the substrate and the comparison step." *Office Action*, page 7. Further, it is the Patent Office's position that "it is critical to have a step evaluating the specificity of the transport." *Office Action*, page 6. Applicants traverse the rejection and submit the following comments.

Without addressing the merit of the Patent Office's rejection, applicants have amended claim 13 to clarify that the assaying step comprises (i) lysing the cell to generate cell lysate; and (ii) detecting the presence of compound in the lysate, wherein the presence of the compound in the lysate indicates the compound is transported by OATP2. Additionally, applicants submit that the clarification that the OATP2 is located in a liver cell or a cell expressing an exogenous OATP2 protein addresses the Patent Office's belief that it is critical to have a step evaluating the specificity of the transport. In this regard, applicants note that OATP2 is the only OATP that is expressed in liver cells (see, e.g., page 45, lines 21-24 of the Specification).

VII. Conclusion

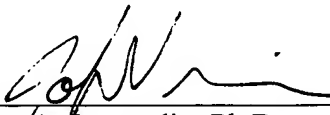
Applicants submit that, in view of the amendments to the claims and the remarks presented herein, the subject application is in condition for allowance. Accordingly, applicants respectfully request that the objections and rejections of record be reconsidered and withdrawn and a Notice of Allowance issued.

Although it is believed no additional fee is due, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment associated with the filing of this correspondence to Deposit Account Number 19-3880. Furthermore, if any extension of time is required, such extension is hereby petitioned for, and it is requested that any fee due for said extension be charged to Deposit Account Number 19-3880.

If any small matter should remain outstanding after the Examiner has had an opportunity to review the above Response, the Examiner is respectfully requested to telephone the undersigned attorney in order to expeditiously resolve these matters.

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Respectfully submitted,



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